MAR 3 1 2004

K040561

510(k) SUMMARY

Shanghai Wheelchair Factory's
Manual Wheelchair Series

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Shanghai Wheelchair Factory
80 Lane 251 Zoayang Road
Shanghai, China 200062
Phone: 86-21-62542392
Fax:86-21-62168882

Contact Person:

Tracy Ma
Representing Shanghai Wheelchair Factory
Project Manager
Vendor Development Group, Inc.
120 Ionia Street SW
Grand Rapids, MI 49503

Date Prepared:

February 28, 2004

Name of Device and Name/Address of Sponsor

Manual Wheelchair Series

Vendor Development Group, Inc.
120 Ionia Street SW
Grand Rapids, MI 49503
Phone: (8770 836-3673
Fax: (616) 459-9850

Common or Usual Name

Manual Wheelchair

Classification Name

Wheelchair, Mechanical

Predicate Devices
The Shanghai Series Manual Wheelchairs are substantially equivalent to are Invacare's Model "Action Patriot" Manual Wheelchair (K930803) and Sunrise Medical' s Model "Breezy 510" Manual Wheelchair (K974820)

Intended Use
The intended use of the Manual Wheelchair Series is to provide mobility to persons limited to a sitting position.

Technological Characteristics and Substantial Equivalence

A. Device Description
The Manual Wheelchair Series are manually operated, self or attendant propelled, manual, mechanical wheelchairs. Their intended function and use is to provide mobility to persons limited to a sitting position. The products may also be used as attendant propelled patient transport devices in a health care environment such as hospital, nursing homes, or extended care facilities.

The products consist primarily of a metal frame, large rear wheels with hand rims for propelling the chair, and smaller front pivoting casters for steering and turning. There is also an attendant propelled version (Model 0400), which has smaller rear wheels than the others in the series.

B. Substantial Equivalence
The Shanghai Series Manual Wheelchairs are substantially equivalent to Invacare's Model "Action Patriot" Manual Wheelchair (K930803) and Sunrise Medical' s Model "Breezy 510" Manual Wheelchair (K974820)

PERFORMANCE DATA
The Manual Wheelchair Series meet the applicable requirements specified in part 8 of the ISO Standard ISO 7176: 1993(E), "ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Shanghai Wheelchair Factory
C/o Ms. Tracy Ma
Project Manager
Vendor Development Group, Inc.
120 Ionia Street SW
Grand Rapids, Michigan 49503

Re: K040561
Trade/Device Name: Manual Wheelchair Series
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: January 29, 2004
Received: March 5, 2004

Dear Ms. Ma:

This letter corrects our substantially equivalent letter of March 31, 2004 regarding the device named above. The Trade/Device Name was incorrectly listed as Shanghai Series Manual Wheelchairs. The correct Trade/Device Name is listed above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040561

Device Name: Manual Wheelchair Series

Indications For Use:

The intended use of Shanghai Wheelchair Factory's Manual Wheelchair Series is to provide mobility to persons limited to a sitting position.

FAXED 4/5

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040561

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)